2401 West Belvedere Avenue
Baltimore, MD 21215-5271
www.lifebridgehealth.org
410-601-5134
410-601-9487 fax

Warren A. Green
President and
Chief Executive Officer

May 24, 2007

David A. Neumann, Ph.D.
Health Policy Analyst
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Re: Draft Proposed COMAR 10.24.05 - Research Waiver Applications for Participation in the Atlantic Cardiovascular Patient Outcomes Research Team Study of Non-Primary Percutaneous Coronary Interventions Performed in Maryland Hospitals without On-Site Cardiac Surgery

Dear Dr. Neumann:

This letter sets forth the comments of LifeBridge Health, Inc. ("LifeBridge") on the above-referenced draft proposed regulations (the "Proposed Regulations"). LifeBridge Health is the largest and most comprehensive provider of health-related services in Northwest Baltimore, and includes Sinai Hospital, Northwest Hospital, and Levindale Hospital. Sinai Hospital offers both open heart surgery and angioplasty services.

PRELIMINARY MATTERS

Inclusion of Documents in the Public Record

The Commission has received previous correspondence from LifeBridge Health, as well as from other sources, regarding the Atlantic C-PORT Study of Non-Primary Percutaneous Coronary Interventions Performed in Hospitals without On-Site Cardiac Surgery (hereinafter the "Study" or the "C-PORT Study") . It is requested that the following communications be included in the public record, if they have not already been made a part thereof:

- Letter dated April 16, 2007 from Lyndon L. Bailey, President of Mended Hearts, Chapter 168 to Gail R. Wilensky, Ph.D., Vice-Chair, Maryland Health Care Commission

- Letter dated January 12, 2007 from Barry F. Rosen to Rex W. Cowdry, M.D.

- All reports of the Data and Safety Monitoring Board with respect to the ongoing C-PORT Study.

Reservation of Rights

While LifeBridge has previously communicated that it believes that the C-PORT Study should not move forward for ethical and other reasons, it is nevertheless taking this opportunity to comment on the Proposed Regulations. However, these comments should not be construed as an admission that the Study should move forward in Maryland, and LifeBridge reserves its rights to further challenge the Study.

COMMENTS

These comments follow the structure of the Proposed Regulations. For each comment, the language of the applicable section is included in bold, followed by a brief statement of the proposed change in italics, and then in most cases a discussion of the reasons for the proposed change. At the conclusion of this comment section are additional general comments about the regulations.

10.24.05.02.C

The Commission may grant a waiver from Policy 5.0 of COMAR 10.24.17.04E for no more than six (6) hospitals without on-site cardiac surgery to perform the non-primary PCI as part of the C-PORT Study.

The number of waivers should be allocated based on region, and each region should have at least one waiver slot. Further, for the Baltimore Metropolitan Region and the Washington Metropolitan Region, where access to PCI is of no concern, substantial additional justification must be provided to have more than one waiver in either area.

The Commission and the Staff have previously expressed the view that a primary reason for allowing elective PCI is to improve the ability of rural hospitals to perform primary PCI. It therefore follows that the majority of waiver sites for elective

PCI should be granted to rural hospitals. Moreover, in all of Maryland, but particularly in the metropolitan regions, the Commission's own experts have determined that access to elective PCI is not a problem.[1] Therefore, in the metropolitan regions, where the vast majority of residents are within 20-30 minutes of a heart center, the Commission should not issue more than one waiver per region unless there is substantial additional justification for exposing patients to the risk associated with performing *elective* PCI without cardiac surgery back-up in the absence of any corresponding benefit.

10.24.05.03.B(1)

A hospital without on-site cardiac surgery in the Metropolitan Baltimore or Metropolitan Washington regional service area may file an application for a waiver to perform non-primary PCI services within the C-PORT Study if, at the time of application, the hospital has a 2-year waiver to perform primary PCI.

An additional requirement for a hospital in these regions to be eligible to file an application should be that the applicant is at least five miles from a hospital that offers open heart surgery.

Many of the hospitals in the Metropolitan Baltimore or Washington regions are located very near existing heart centers. There is no justification for allowing these hospitals to perform elective PCI when a hospital with cardiac surgery back-up is literally minutes away. Further, for the hospitals within these regions that currently perform primary PCI, these hospitals typically draw their interventional cardiologists from the same pool of interventionalists that serve the nearby heart centers, so allowing elective PCI at these centers will not account for any significant improvements to the primary PCI services they offer.

In addition, the volume of elective PCI procedures at metropolitan hospitals participating in the Study is likely to exceed the volume at participating rural hospitals. Because volume is so closely related to quality,[2] the outcomes experienced by metropolitan hospitals are unlikely to be indicative of the outcomes

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[1] *See* Advisory Committee on Outcome Assessment on Cardiovascular Care, Final Report, dated June 19, 2003, p. 20.

[2] *See, e.g.*, Smith, S.C. et al., ACC/AHA/SCAI 2005 Guideline update for percutaneous coronary intervention, American College of Cardiology, Washington DC and American Heart Association, Dallas, TX (hereinafter the "Guidelines"), p. 35 ("The Writing Committee cannot recommend angioplasty by low-volume operators (fewer than 75 cases per year) working in low-volume institutions (200 to 400 cases per year) with or without onsite surgical coverage.").

that may be experienced by low volume rural hospitals, so the results of the Study, if heavily weighted with data from higher volume urban hospitals, will be meaningless with respect to rural hospitals.

10.24.05.03.B(2)

A hospital without on-site cardiac surgery in the Eastern Shore or Western Maryland regional service area may file an application for a waiver to perform non-primary PCI services within the C-Port Study if, at the time of application, the hospital has a waiver to perform primary PCI, has provided PCI services for at least six months, and has completed a minimum of 18 primary PCI procedures.

The criteria of having performed 18 primary PCI procedures will by no means measure the ability of the applicant to perform 200 PCIs a year, which is required under the regulations to retain a waiver. Therefore, these programs should have to meet the higher standard of 25 primary PCIs performed within the six months preceding the application.

Because elective PCI is never an "emergency", all hospitals performing it should have to meet quality standards, which include maintaining a minimum volume of, at the very least, 200 PCIs performed annually[3]. It is well established that, with respect to PCI, volume is directly related to outcomes. While it may make sense to allow rural hospitals with low volumes to provide primary PCI – because time is critical to the success of the procedure - it would never make sense to allow these hospitals to perform elective, non-emergency PCI. Further, because these rural hospitals still must meet the 200 PCI volume requirements to maintain their waiver and to continue in the Study, allowing them to apply for and possibly obtain a waiver based on lower volumes will only be setting them up for expulsion from the Study, which of course will affect the Study's ability to provide meaningful and reliable data.

10.24.05.04.A(2)(b)

Physician Resources. An application must document that it has or will recruit adequate staff necessary for the provision of primary and non-primary PCI services, including a minimum of three interventional cardiologists...

Three interventional cardiologists will leave no room for illness, vacation or conflicting schedules. Accordingly, requiring four or five interventional cardiologists would be more appropriate.

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[3] The Guidelines state that elective PCI should not be performed at hospitals with fewer than 400 PCIs per year. *See* Guidelines, p. 35.

10.24.05.04.A
Review Criteria

In addition to the criteria set forth in this section, the Proposed Regulations should also require that an applicant demonstrate that at least 267 patients who meet the strict participant inclusion criteria of the Study will present to the hospital each year.

This requirement is similar to the requirement that a hospital applying for a primary waiver must demonstrate that it has a minimum of 60-65 and optimally 85-90 acute ST-segment elevation MIs annually, and is vital in determining whether an applicant is likely to meet the participant enrollment requirements of the Study. In its projections, the Study anticipates that each hospital will enroll 200 elective PCI patients into the Study per year.[4] Note that 267 is the lowest number necessary to cover the 1 to 3 randomization of the Study and still maintain a volume of 200. This number should in actuality be higher than 267 to compensate for eligible patients who decline to participate in the Study. Moreover, since the Study uses the full 200 of each hospital's required PCI volume in projecting the number of enrollees and the length of the Study, the number of primary PCI patients a hospital expects to treat should not be included in the 267.

The Study's success is largely dependent on the ability of participating hospitals to meet these volume levels. Failure to do so will extend the life of the Study well beyond the originally projected 28 months and significantly increase costs. In addition, since many states' regulations, like the Proposed Regulations, make meeting the 200 procedure volume requirement a condition of allowing a hospital to participate in the Study, failure of a hospital to meet this requirement will have a double impact on the results of the Study, because if an underperforming hospital loses its state approval to participate, the Study accrual numbers will be reduced by the hospital's full volume. Requiring an applicant to demonstrate that it can meet these criteria is therefore necessary if the Study is to provide reliable results.

The Proposed Regulations should also require that the hospital demonstrate that, in the event a patient experiences a complication requiring a transfer to a heart center, such a transfer can be accomplished in 60 minutes or less.

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[4] *See* C-PORT Study (Version 3.0 – March 29, 2006), p. 15. *See also* Recommendation of Rex Cowdry, MD, MPH, Executive Director to Commissioners, Maryland Health Care Commission regarding C-PORT Proposal to Study Non-Primary (Elective) PCI Performed in Maryland Hospitals without On-Site Cardiac Surgery, dated April 13, 2007 (the "Recommendation"), p. 8.

Although the Study requires a 60-minute transfer time for participating hospitals, it notes that the requirement *may be waived* for hospitals in rural settings. Transfers to a heart center will generally only occur when life-threatening complications arise. The Commission should not allow the Study investigators to waive the 60-minute transfer time for any Maryland hospital.

10.24.05.04.A(2)(c)

Minimum Volumes. An applicant must document that it will meet and maintain a minimum volume of 200 PCI procedures annually.

A volume requirement of 200 PCIs is the absolute minimum the Commission should allow, and the Commission should consider increasing this volume limit for applicants in the metropolitan regions.

The Study suggests that the volume requirement of 200 PCIs annually may be waived for some rural hospitals. The Commission should not allow anything less than 200 PCIs annually, even for rural hospitals. A volume level of 200 is already significantly below the volume of 400 suggested by the Guidelines[5]; it should not be lowered any further. Moreover, the Commission should consider requiring a higher number of annual PCI procedures for applicants in the metropolitan areas, to bring the volume levels closer to those suggested by the Guidelines.

10.24.05.04.A(3)

In determining whether to grant a waiver application, the Commission may consider appropriate factors, including:

(a) An applicant's potential to improve the geographic distribution of cardiovascular services;

(b) An applicant's potential to increase access to PCI services for minorities and medically underserved populations;

(c) An applicant's ability to serve as a site for conducting research;

(d) An applicant's demonstration of successful and timely acquisition of follow-up data on primary PCI patients; and

(e) An applicant's current performance under its primary PCI waiver.

*The Commission should be **required** to consider the above factors in determining whether to grant a waiver.*

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[5] *See* Guidelines, p. 35.

The factors set forth in this section either (1) speak to the very reasons the staff and the Commission have cited for allowing the Study to proceed (factors a and b), or (2) speak to whether the Study will be successful (factors c, d, and e).

In addition to the above cited factors, the Commission should also be required to consider whether granting a waiver application will: 1) have an adverse impact on existing elective PCI providers; 2) raise the cost of health care in the State; or 3) cause or contribute to a shortage of the highly trained staff necessary to run catheterization labs.

Many of these concerns have previously been raised by the Commission as real concerns regarding the de-centralization of angioplasty services in the State. Selection of certain waiver sites will have a definite negative impact on some heart centers. Pulling volume from a strong heart center to bolster volume at a nearby community hospital will only serve to decrease overall quality of care in the State, by creating a pool of mediocre providers versus having a select number of centers of excellence. Further, evidence establishes that, due to economies of scale, the cost to perform elective PCI is significantly greater ($6,084 per procedure in 2002) at low volume hospitals than at high volume hospitals. Finally, there is a finite number of highly qualified interventional cardiologists and staff necessary for performing PCIs and running catheterization labs. Broadening the field of hospitals providing such services will only serve to create bidding wars for these physicians and staff.

Lastly, before granting any waivers, the Commission should be required to consider whether the C-PORT Study, based on its historical performance in other states, is likely to produce reliable results. Specifically, the Commission should evaluate the Study's performance in the three areas identified by Staff as central to determining the success of the Study – accrual, retention and adverse event reports – as well as funding for the Study to determine if the Study is likely to produce reliable results.

If the Commission promulgates regulations for granting waivers for hospitals to participate in the C-PORT Study, the review of applications will likely not begin until the end of 2007 or the beginning of 2008 (allowing time for the process of approving the regulations). By this time, the C-PORT Study will have been enrolling patients for close to a year and a half (which will represent almost 2/3 of the projected Study period of 28 months). Because the very reason for granting the waiver is to allow participation in the C-PORT Study, the Commission should evaluate the actual performance of the Study to determine if it remains likely to produce reliable results, and this review should be conducted before granting any waiver to participate in the Study. Evaluating the historical results of the C-PORT

Study can be easily accomplished by review of the reports of the Study's Data and Safety Monitoring Board.[6]

Specifically, the Commission should evaluate the historical performance of the Study in the three areas identified by the Staff as crucial to the Study's success – patient accrual, retention and adverse event reports. This is particularly important in light of the fact that the results reported by the Study for 2006 already raise concern that the Study may not meet its own projections. For example, for 2006, the hospitals participating in the Study had an average annualized enrollment of 127 – just 64% of the projected 200 patient enrollments. Although, as Staff notes, most of the hospitals for which 2006 data was collected had only been enrolling patients for about six months, there is no reason to anticipate significant increases in participating hospitals' enrollment experience because enrollment is simply a function of the number of eligible patients presenting to the hospital who consent to participate in the Study.[7] Factors that could increase a hospital's enrollment, such as gaining a reputation as a PCI center or marketing of its PCI services, will not come into play due to the length and nature of the Study. The fact that the 27 participating hospitals only achieved an average annualized enrollment of 127 is particularly troubling considering the Study projected that, based on the number of diagnostic catheterizations performed by the 19 hospitals in New Jersey and Georgia, these hospitals would have an annual enrollment of 240 each.

Retention rates realized by participating hospitals should also be evaluated by the Commission before granting any waiver application. This is particularly important because the Study does not require hospitals to meet any specific retention levels to remain in the Study, although it assumes that hospitals will realize a 100% retention level. Although Dr. Cowdry notes that as of today, it is too early to assess the critical nine-month retention rate, the original 27 participants will have been enrolling patients for well over a year by the time the Commission is considering actual waiver applications. The Commission can and should assess whether the Study is meeting the 98% retention projections before granting any waiver applications. As noted by Dr. Cowdry, retention, like volume and adverse events, can be easily assessed and monitored through the reports of the Study's Data Safety Monitoring Board.

The Proposed Regulations currently provide for tracking adverse events after a waiver is granted. However, as with accrual and retention, the number of adverse

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[6] *See* Recommendation, p.14.

[7] Presumably, these hospitals had to show that they were capable of performing the required 200 elective PCIs before they were admitted into the Study, so the staff's gaining experience should also not be a factor in increasing enrollment.

events experienced by hospitals participating in the Study should be evaluated before the Commission approves any waiver to participate in the waiver. If a significant number of adverse events have occurred, the Commission should reconsider whether to grant any waivers.

Finally, the Commission should conduct a review of the status of the funding of the Study before it approves any waiver to participate in the Study. The Study, originally predicted to last for 28 months (which would mean an end date of mid-2008), is now projected to run much longer, resulting in significant additional costs. However, there is no clear statement of where the necessary additional funding will come from. The current budget for the Study projects three-year expenses of $3,395,269. In his recommendation, Dr. Cowdry notes that the cost of the Study is more likely to be around $4,000,000, and he notes that the ability to meet the costs of the Study is a concern.[8] For that reason, Dr. Cowdry states that funding should be closely monitored after waivers are granted. Presumably, the hospitals that have been participating in the Study since early 2006 have already made their two-year contributions to the Study (which were most likely based on the original Study's cost projection of $34,000 per year and not the revised Study's projected costs of $52,500 per year). Although the hospitals currently participating in the Study may elect to contribute money to support extending the Study beyond the initially projected two years, presumably any agreements to make such additional payments will require an amendment to the contract between such hospitals and the C-PORT team. It should therefore be a simple matter to determine how much of the estimated $4,000,000 in costs has already been funded and how much more the Study is contractually entitled to receive, so as to determine whether the Study is likely to have the funds necessary to realize its objectives.

10.24.05.05.A
A waiver to perform non-primary PCI issued by the Commission will expire on the earlier of:

(1) Two years from the date on which the Waiver was first issued;
(2) The date patient accrual into the C-PORT Study ends;
(3) A finding made by the Commission that the C-PORT Study is not accruing patients at an acceptable rate; or
(4) A finding by the Commission that the C-PORT Study is unlikely to produce reliable results to guide public policy.

With respect to (1), waivers should be granted for a maximum of one year, so that the Commission may monitor whether the applicant is meeting the volume and other requirements of the Study and the regulations.

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[8] *See* Recommendation, p. 14.

Granting only one-year waivers would be consistent with the current process for granting initial waiver applications to perform primary angioplasty. It would also provide a definitive timeframe and process for a re-evaluation of the Study's overall experience and an assessment of the continuing likelihood that the Study will produce reliable results.

With respect to (3) and (4), these findings should be made by the Commission before granting any waiver applications, in addition to being made at the end of each one-year waiver period.

An additional factor that should lead to the early expiration of the waiver is if the C-PORT Study is not realizing retention rates of at least 98%. As with items (3) and (4), this finding should be made by the Commission before granting any waiver applications, in addition to being made at the end of each one-year waiver period.

As with patient accrual, retention rates will be key in determining whether the Study will produce reliable results.

Other Comments on the Proposed Regulations:

1) The Proposed Regulations should allow for comments on applications by interested parties and participating entities.

As mentioned above, the Commission should be required to consider adverse impact on existing providers and the cost implications of granting a waiver to participate in the Study. Accordingly, the Commission should allow interested parties to comment on applications, particularly to demonstrate the impact granting the application will have on the interested party's operations and ability to provide quality medical services. Likewise, the Commission should take comments from participating entities such as payors, particularly with respect to increased costs that may result from granting an application.

The Commission should consider the comments of interested parties and participating entities even though the waivers that will be granted are only to participate in the Study and are theoretically temporary in nature. The Proposed Regulations provide that the Commission may extend a waiver beyond the currently proposed two-year period. Because the Study's lead researcher is already predicting that the Study may last twice as long as was initially projected, it is possible that Maryland waivers may extend well beyond two years. This, coupled with the 1 to 3 randomization scheme of the Study (for every four patients, three patients who ordinarily would have been diverted to a heart center will remain at the

waiver hospital) could lead to significant adverse impact on existing providers, as well as increased costs to payors, despite the "temporary" nature of the waiver.

2) Because the criteria for granting primary PCI waivers is used in part as the basis for granting waivers for elective PCI, the Commission should strictly enforce the primary PCI criteria.

In 2006, the Commission granted several Baltimore Metropolitan and Washington Metropolitan region hospitals conditional one-year waivers. Even though many of these hospitals had been performing primary PCI for several years (under the original C-PORT Study), the Commission did not grant these hospitals two-year waivers because of their failure to meet one or more of the criteria established for primary waiver hospitals, such as door to balloon time and volume requirements. Most of these hospitals have filed or are likely to file applications to renew their primary waivers. The Commission should strictly enforce the primary PCI criteria and refuse to renew the waiver of any hospital that does not meet the criteria.

3) The Proposed Regulations should specifically state that the costs associated with a hospital's participation in the C-PORT Study may not be used as a basis for an increase in the hospital's rates.

The total cost of participation in the Study is expected to be $270,000 - $395,000 per hospital (including internal personnel costs in addition to the $52,500 per year participation fee).[9] Depending on the hospital, this amount may have a significant impact on the hospital's financial position. These costs should not be considered in any rate review of any participating hospital.

CONCLUSION

LifeBridge believes that the implementing the foregoing comments will better adhere to the amendments to Dr. Cowdry's recommendation that were proposed by Commissioner Row and adopted by the Commission on April 19, 2007 - namely,

[9] *See* Recommendation, p. 14 (noting that total estimated costs of the study would be more than $10 million to $15 million if the participating hospitals' costs were included).

ensuring that the Proposed Regulations are drafted in a manner that will achieve "strong volumes, cost effectiveness, and improvement in geographic access."

We appreciate the opportunity to provide comments on this draft.

Sincerely yours,

Warren A. Green

GORDON • FEINBLATT
ROTHMAN, HOFFBERGER & HOLLANDER, LLC

BARRY F. ROSEN
410.576.4224
FAX 410.576.4032
brosen@gfrlaw.com

ATTORNEYS AT LAW
233 EAST REDWOOD STREET
BALTIMORE, MARYLAND
21202-3332
410.576.4000
www.gfrlaw.com

January 12, 2007

Rex W. Cowdry, M.D.
Executive Director
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore MD 21215

Re: Review of Elective Angioplasty Study

Dear Dr. Cowdry:

This letter is written on behalf of St. Joseph Medical Center, MedStar Health and LifeBridge Health to ask you to recommend that the Maryland Health Care Commission reject Dr. Aversano's proposed study.

Dr. Aversano proposes to study the safety and efficacy of performing elective percutaneous coronary intervention (PCI) at hospitals that do not have cardiac surgery on site (SOS). The study is *nontherapeutic* in that it provides *no* clinical benefit to the study participants.

In contrast to the original C-PORT study, the study participants in Dr. Aversano's elective angioplasty study are not in a life-threatening situation. The angioplasty is by and large an elective, scheduled, procedure. Even in situations where the angioplasty needs to be performed soon after a diagnostic catheterization, the amount of time between the diagnostic catheterization and the PCI is not critical to the outcome. The only potential benefit to participants in Dr. Aversano's study is convenience.

Ironically, the stated goal of the study is to demonstrate its lack of clinical benefit. Its aims are to demonstrate that the incidence of death, myocardial infarction or other complications are *not greater*, and clinical success rates are *not lower*, for elective PCI at hospitals without SOS versus elective PCI performed at hospitals with SOS. In other words, the *best* outcome of the study is a showing that patients in the study group are not clinically *harmed* by their participation in the study.

Unfortunately, as well intended as Dr. Aversano's study may be, it violates the ethical and legal principle known as *equipoise*. "Research equipoise means that there is a genuine uncertainty on the part of the medical community about which intervention – experimental or control – is *better*. An experimental intervention may pose greater risk to participants than accepted practice, as long as it also offers the prospect of greater direct benefit to the participant."[1] However, subjects should never be put at significant risk when, as in the situation at hand, the experimental intervention is believed to be *inferior*.

The most significant study in this field has found that patients undergoing elective PCI in hospitals without SOS are 38% more likely to die than patients undergoing elective PCI in hospitals with SOS.[2] Moreover, the national guidelines of the American Heart Association, the American College of Cardiology and the Society for Cardiovascular Angiography and Intervention all agree that performing elective PCI without SOS potentially compromises patient safety, and thereby exposes participating doctors and hospitals to expensive claims of medical malpractice.[3]

You have stated that the Aversano study is being considered because the Commission does not know for sure if elective PCI at hospitals without SOS is as safe. Dr. Aversano does not know either. Otherwise, there would be no need for the study. Therefore, the proposal has two possible outcomes, one of which unfortunately is proving that PCI at sites without SOS is not as safe. If that is the outcome of the study, then sadly there may be Marylanders who will die because the Commission approves this study.

In this regard, it is important to remember the following about research ethics:

> "The topic of research ethics needs to be mentioned. It is not an esoteric branch of philosophy. It is not the domain of 'ethics specialists.' It is not the experience of appearing before an Institutional Review Board to answer questions about a protocol. It is not studying to pass a multiple-choice test to qualify as an investigator. It is, instead, a way of thinking about our responsibilities to one another – about respect, truthfulness, caring and collaboration. It is vital that this mode of thinking, this effort

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[1] *See Ethical and Policy Issues in Research Involving Human Participants* (National Bioethics Advisory Comm'n, Bethesda, MD), Aug. 2001, Vol. 1, at 78, Exh. 4.1.

[2] *See Outcomes of Percutaneous Coronary Interventions Performed at Centers Without and With Onsite Coronary Artery Bypass Graft Surgery*, Wennburg, D.E., et al., JAMA, Vol 292, No. 16, 1061, October 7, 2004. This study noted that the increase in mortality was primarily confined to hospitals performing 50 or less PCIs per year.

[3] *See Risky Practice*, September 2, 2006, jfauber@journalsentinel.com, a copy of which is attached.

> to put oneself in the position of a research participant and consider the person/patient's best interest, be modeled by mentors and become an integral part of the learning experience of the researcher-in-training.
>
> Learning a fundamental regard for the long-term well-being of the patient will help avoid the worst examples of research – research driven by curiosity or ambition that treats the patient as a means to an end, research that needlessly prolongs distress because of the protocol design, or researchers who lose interest after the last day of the study – in short, research that an investigator would not recommend to his or her own loved ones if they were similarly affected by the illness."[4]

Would you recommend to your loved ones to have elective angioplasty at a site without open heart surgery backup? Moreover, as called for in the Aversano Proposal, would you recommend elective angioplasty at a site without cardiac backup to three out of four of your loved ones? If not, then we hope you will recommend that the Commission reject the Aversano Proposal.

Yours truly,

Barry F. Rosen

Enclosure

cc: Stephen Salamon, Chairman, Maryland Health Care Commission

[4] *Commentary–Research – An Admirable Ally*, Cowdry, Rex W. Academic Psychiatry 25:12-14 March 2001.

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A risky practice?

As more angioplasties are performed, some doctors want patients to know that not having a heart surgeon on site can be dangerous

By JOHN FAUBER
jfauber@journalsentinel.com

Posted: Sept. 2, 2006

When her cardiologist recommended a heart catheterization and possible angioplasty, Patricia Stropes refused at first.

"We turned it down twice," said her husband, Stephen Stropes. "I didn't like the odds."

But after several days at what is now Wheaton Franciscan Healthcare-All Saints in Racine, where she had been admitted with shortness of breath, she reluctantly agreed.

" 'Let's do it and get it over with, so I can go home,' " Stephen Stropes recalled his wife saying.

On the morning of June 29, 2004, she was taken into the cardiac catheterization lab. A short time later, Stephen Stropes was frantically summoning their daughter to the hospital.

"All I said was, 'Jenny.' She said, 'I'll be right there, Dad,' " he recalled.

As cardiologist Cornell Cohen tried to place a stent in one of Patricia Stropes' coronary arteries, the balloon and wire became lodged in the artery, according to medical records. Stephen Stropes said Cohen told him that in doing the procedure, he had torn the artery.

Doctors feared cardiac tamponade, a condition in which the sac surrounding the heart fills with blood, squeezing the heart's chambers and preventing them from pumping properly.

Patricia Stropes, 71, needed a heart surgeon and fast.

What the Racine couple didn't know, Stephen Stropes said, was that on that day, the surgeon and some of his support team would have to be called from Aurora St. Luke's Medical Center in Milwaukee, 27 miles away.

"If I had known what I was doing, I would have said discharge her and we'll go up to St. Luke's Hospital," Stropes said.

As her husband of 51 years waited with other family members, Patricia Stropes died later that day in the operating room.

Whether the surgeon's distance from the hospital made any difference is not known. But the case illustrates how complications in these procedures - however rare - can be catastrophic.

Doctors say they are concerned about the growing number of angioplasties being done at hospitals that might not have a heart surgeon and support staff to perform emergency surgery to save the patient.

National medical practice guidelines say that elective angioplasty - done when the patient is not having a heart attack - should not be performed at hospitals that do not have on-site heart surgery backup.

Patients don't know to ask

Charles Reuben, a Milwaukee heart surgeon, said he suspects that many patients undergoing elective angioplasty at hospitals without a heart surgeon on duty are never told that if there is a problem, their lives might depend on how quickly they can be transferred to another hospital or how quickly a surgeon can be brought in.

Reuben practices at Wheaton Franciscan Healthcare-St. Joseph in Milwaukee, which has a heart surgery program.

Doctors say patients should ask this question about where they have an elective angioplasty: Would they rather a have heart surgeon on duty in case of a problem, or is it acceptable if they are urgently transferred out by ambulance or helicopter or that a surgical team has to be called in from another city?

"If I had angioplasty . . . I'd rather have it done where there's a heart surgeon and a team in the hospital," Reuben said.

Most patients sail through the procedure, which is lucrative for the hospitals. In 2003, 664,000 angioplasties were performed in the United States at average cost of $38,000 each, according to the American Heart Association. From 1987 to 2003, the number of angioplasties increased 326%.

Nationally, the in-hospital death rate for all angioplasties was 0.8%. That includes deaths that occur after emergency, or so-called primary, angioplasty, which is performed when the patient is suffering an actual heart attack. The vast majority of angioplasties are elective.

Higher mortality rate found

Although angioplasty has become safer since the 1980s, research suggests, emergency heart surgery still is needed in 0.4% to 2% of cases.

In the largest study of the issue, researchers found a 38% higher mortality rate in elective angioplasties performed at hospitals that don't perform heart surgery. The 2004 study analyzed 625,854 Medicare-paid angioplasties at 1,121 hospitals.

Elective angioplasty "performed at hospitals without cardiac surgery may be doing more harm than

good," the authors conclude.

The national guidelines, put out jointly by the American Heart Association, the American College of Cardiology and the Society for Cardiovascular Angiography and Intervention, say that "performance of elective (angioplasty) in a setting without immediately available onsite cardiac surgery potentially compromises patient safety."

Several smaller hospitals in Wisconsin that do not have heart surgery programs, however, are offering elective angioplasty.

Several cardiologists interviewed for this story said hospital marketing executives and administrators are pushing cardiologists to perform the procedures in spite of the guidelines.

"A lot of CEOs want it to happen . . . for revenue and ego," said Matthew Wolff, chief of cardiovascular medicine at the University of Wisconsin School of Medicine and Public Health in Madison. The cardiologists "are going against their own guidelines, and they are put in a very difficult position. They (hospital executives) say, 'Either you do it, or we'll get someone else to do it.' "

'Safe to do in stable patients'

Some of the doctors who do the procedures say they can be performed safely at hospitals without cardiac surgery programs with low-risk patients and proper preparation.

At Beloit Memorial Hospital, an ambulance stands by each day that angioplasties are performed, waiting to take any heart patient to Rockford, about a half-hour away, said Larry Bergen, director of cardiovascular services at the hospital. In more than three years, there have been no emergency transports, he said.

Doctors point out that setting up an operating room can take 30 minutes and, by that time, the patient can be taken by medical helicopter or ambulance to another hospital with an available heart surgeon.

"In experienced hands, it's safe to do in stable patients," Milwaukee cardiologist Tanvir Bajwa said.

Bajwa does 600 to 700 angioplasties a year, mostly at Aurora St. Luke's. He also has been doing them at Beloit Memorial and will start doing them at Aurora Sheboygan Memorial Medical Center soon. Neither has on-site heart surgery backup.

In more than three years and 300 elective procedures at Beloit Memorial, there have been no serious complications, Bajwa said - "zero mortality."

Lawsuit claims negligence

In May, Stephen Stropes filed a medical malpractice lawsuit against Cohen, the cardiologist. Neither the hospital nor any other physicians were named as defendants.

In documents filed this year with the Wisconsin Medical Mediation Panel, Stropes' attorney, J. Michael End, argued that Cohen's negligence resulted in Patricia Stropes' death.

End wrote that Stropes would be willing to settle the case for $370,000.

Cohen, who now practices in New York, declined to comment for this article. His attorney, John A. Nelson, said in papers he filed that Cohen met all required standards of care in his treatment of Patricia Stropes.

Acknowledging the "profound effect on the patient and family," Nelson said the complications that occurred during the procedure were known as potential complications. Cohen acted "swiftly, appropriately and decisively" in treating her and coordinating her surgical intervention, he said.

J. F. Tierney, another cardiologist who practices at the hospital and reviewed the case six months later, wrote that the amount of time it took to get Stropes into surgery was "not excessive and the complication, although rare, was not felt to be an operator issue."

The heart surgeon who was called down from Milwaukee is Thomas Barragry, who practices at Aurora St. Luke's in Milwaukee. All Saints has a heart surgery program; records in the case do not explain why a closer surgeon was not available that day.

Barragry said he did not recall all the details of the case.

In general, he said, it can take up to an hour to set up an operating room, so the distance a heart surgeon has to travel is not always crucial. At larger hospitals such as St. Luke's, an operating room can be made available in 30 minutes, he said.

"In general, you have to worry about smaller programs not being able to handle emergencies from a cath lab in as expeditious manner as larger centers," he said.

Would the outcome in the Stropes case have been different had he not needed to travel to Racine from Milwaukee?

"I have no idea," Barragry said.

Definition of 'on site' unclear

Although national medical guidelines call for "immediately available onsite cardiac surgery," two cardiologists who helped draft the guidelines said there is no definition of what *on-site* means.

The distance that Barragry had to travel did not seem like it would qualify as on-site, said Elliott Antman, a professor of medicine at Harvard Medical School and chairman of the guidelines task force.

"It sounds like too far away," Antman said. "Why not have the patient in Racine go into Milwaukee (for the angioplasty)? What's the rationale for putting that patient through that risk?"

In such cases, heart surgeons should be able to get into the operating room promptly, ideally within 15 or 20 minutes, said Sidney Smith, a professor of medicine at the University of North Carolina at Chapel Hill and chairman of the guidelines writing committee.

Carol Meils, the director of cardiology at All Saints, said the standard of care at All Saints is comparable to other hospitals in southeastern Wisconsin. She interprets the on-site guidelines as meaning the surgeon should be within 45 minutes of getting to the operating room.

"The guidelines are really vague," Meils said.

Glyndon L. Bailey, President
Mended Hearts, Chapter 168
8227 Burnley Road
Towson, Maryland

April 16, 2007

Gail R. Wilensky, Ph.D., Vice-Chair
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Dear Dr. Wilensky:

I am writing to express my concern about the proposed study to allow elective angioplasty to be performed without open heart surgery backup on site. As the President of Mended Hearts, Inc., a national nonprofit organization affiliated with the American Heart Association, I am very concerned that Maryland's heart patients will see a lower quality of care than they now receive at hospitals with open heart surgery on site.

Mended Hearts is made up of the very kinds of people the study would impact - heart patients, their families, and others impacted by heart disease. Our support groups help people understand that there can be a rich, rewarding life after a diagnosis of heart disease. Mended Hearts has been offering the gift of hope to heart disease patients, their families and caregivers for more than 50 years.

That is why I am so concerned about this study. It seems to measure how many more patients will be harmed than in current heart hospitals, and I do not see how that can offer hope to any patient. I know that Maryland allows emergency patients to be seen at any hospital if they need emergency angioplasty, and I support that, no matter what the risk. There is no such need, however, for elective angioplasty, as there is no emergency.

Just because technology has improved and has made angioplasty safer does not mean that it should be done at hospitals without open heart surgery back-up. If you or your loved one, or me or my loved one, happens to be the one who needs open heart surgery, we would not feel that it is safer when we could have gone to a hospital with on-site backup for an elective procedure.

Current American College of Cardiology standards require open heart surgery backup, I think the Maryland Commission should follow the advice of national experts. Heart patients should not be exposed to additional harm for any reason, when we already know that they are not harmed now, especially in a small state like Maryland where we have so many high quality heart centers.

Please reconsider your adoption of this dangerous program and contact me at 410-769-8049 if you would like to speak further about my concerns.

Sincerely,

Glyndon L. Bailey

cc: Rex Cowry, Ph.D., Executive Director,
Maryland Health Care Commission